K001976

DEC - 6 2000

PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.92)

807.92 (a):

1. *Submitter's Name:* STC Technologies, Inc.
   Address: 1745 Eaton Avenue, Bethlehem, PA 18018
   Telephone Number: (610) 882-1820
   Contact Person: R. Sam Niedbala, Ph.D., BCFE
   Date Prepared: June 26, 2000

2. *Device Name:*
   Proprietary Name: Barbiturates Intercept™ MICRO-PLATE EIA
   Usual Name: Barbiturates Intercept™ System
   Classification Name: Enzyme Immunoassay, Barbiturate

3. *Device to Which Substantial Equivalence Is Claimed:*
   Roche Diagnostic Systems, Abuscreen ONLINE® kit for barbiturates (urine); K914468

4. *Description of Device:*
   Principle of the Assay
   The STC Barbiturates Intercept™ MICRO-PLATE EIA is a competitive micro-plate immunoassay for the detection of barbiturates in oral fluid collected with the Intercept™ DOA Oral Specimen Collection Device. Specimen or standard is added to an EIA well in combination with an enzyme-labeled hapten derivative. In an EIA well containing an oral fluid specimen positive for barbiturates, there is a competition between the drug and the enzyme-labeled hapten to bind the antibody fixed onto the EIA well. EIA wells are then washed, substrate is added, and color is produced. The absorbance measured for each well at 450 nm is inversely proportional to the amount of barbiturates present in the specimen or calibrator/control. Because currently there are no SAMHSA assigned cutoffs for barbiturates testing using oral fluid, STC recommends a cutoff of 20 ng/mL when testing oral fluid collected with the Intercept™ DOA Oral Specimen Collection Device. This cutoff is within the limit of detection by the STC Barbiturates Intercept™ MICRO-PLATE EIA.

5. *Intended Use Statement:*
   The STC Barbiturates Intercept™ MICRO-PLATE EIA is intended for use by clinical laboratories in the qualitative determination of barbiturates in oral fluid collected with the Intercept™ DOA Oral Specimen Collection Device. **For In Vitro Diagnostic Use.**

   The STC Barbiturates Intercept™ MICRO-PLATE EIA provides only a preliminary analytical test result. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when a preliminary, positive result is observed.

6. a. *Summary of Technological Characteristics:*
   The STC Barbiturates Intercept™ MICRO-PLATE EIA is based on the principle of solid phase competitive enzyme immunoassay. This application is for the use of the STC Barbiturates Intercept™ EIA as a screening tool for the detection of barbiturates using specimens collected with the Intercept™ DOA Oral Specimen Collection Device manufactured by Epitope, Inc., Beaverton, Oregon.

b. *Summary of Performance Data:*

The performance characteristics of the STC Barbiturates Intercept™ MICRO-PLATE EIA are summarized below. This information concludes that the performance of this device is essentially equivalent to the legally marketed predicate device.

	Proposed: Barbiturates Intercept™ MICRO-PLATE EIA	**Predicate (K914468):** Abuscreen ONLINE for Barbiturates
Performance Characteristics:		
Precision		
Intra-assay %CVs	0 ng/mL: 4.1 10 ng/mL: 4.4 20 ng/mL: 3.8 30 ng/mL: 7.1 40 ng/mL: 4.9	100 ng/mL: 3.7 150 ng/mL: 2.5 200 ng/mL: 1.5 250 ng/mL: 1.8 300 ng/mL: 0.8
Inter-assay %CVs	0 ng/mL: 8.5 10 ng/mL: 8.9 20 ng/mL: 8.9 30 ng/mL: 8.9 40 ng/mL: 9.4	100 ng/mL: 5.5 150 ng/mL: 3.4 200 ng/mL: 2.6 250 ng/mL: 2.6 300 ng/mL: 4.2
Limit of Detection	8.2 ng/mL	20 ng/mL
% Cross-Reactivity		
Allobarbital	23.6	61
Amobarbital	43.3	28
Aprobarbital	28.9	68
Barbital	9.1	21
Barbituric acid	Not tested	0
Butabarbital	184.7	41
Butalbital	109.7	40
Cyclopentobarbital	Not tested	95
1,3-Dimethylbarbituric acid	Not tested	0
Diphenylhydantoin	Not tested	0
Glutethimide	Not tested	0
Hexobarbital	0.1	0
p-Hydroxyphenobarbital	Not tested	27
Mephobarbital	0.1	< 1
Methohexital	0.01	Not tested
Pentobarbital	68.0	35
Phenobarbital	50.0	32
Talbutal	170.4	Not tested
Clinical Accuracy	97.6% agreement as compared to GC/MS.	N=74 confirmed positive. 74 positive, 0 negative

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 6 2000

R. Sam Niedbala, Ph.D., BCFE
Chief Science Officer
STC Technologies, Inc.
1745 Eaton Avenue
Bethlehem, Pennsylvania 18018-1799

Re: K001976
Trade Name: STC Barbiturates Intercept™ MICRO-PLATE EIA
Regulatory Class: II
Product Code: DIS
Dated: October 25, 2000
Received: October 26, 2000

Dear Dr. Niedbala:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K001976

Device Name: STC Barbiturates Intercept™ MICRO-PLATE EIA

Indications For Use:

The STC Barbiturates Intercept™ MICRO-PLATE EIA is intended for use by clinical laboratories in the qualitative determination of barbiturates in oral fluid collected with the Intercept™ Drugs of Abuse (DOA) Oral Specimen Collection Device. FOR *IN VITRO* DIAGNOSTIC USE.

The STC Barbiturates Intercept™ MICRO-PLATE EIA provides only a preliminary analytical test result. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when a preliminary, positive result is observed.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001976

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)